

REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-21 are pending in this application. Claims 1, 2 and 5 have been amended to substitute numbers for dashes. Claims 22 and 23 have been cancelled. It is believed that no new matter has been added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. BASIS FOR RESTRICTION HAS NOT BEEN ESTABLISHED BY THE OFFICE

MPEP 803.01 states that there are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent...or distinct as claimed...; and
- (B) There must be a serious burden on the examiner if restriction is required...

While the Examiner has articulated her reasons why the inventions are independent or distinct, there has been no discussion as to why having independent and distinct inventions within the same application presents a serious burden on the Examiner.

MPEP 803.01 also states that "[i]f the search and examination of an entire application can be made without serious burden, *the examiner must examine it on the merits*, even though it includes claims to independent or distinct inventions." (Note: Merely asserting that the independent or distinct inventions can be classified in different class/subclasses is insufficient to establish a serious burden as it is routine practice (which is evident in any number of issued patents) to search multiple class and subclasses during examination.)

As there is no basis for establishing a serious burden on the examiner, each of the remaining claims must be examined and the restriction should be withdrawn.

Should the finality of the restriction be maintained, the applicants reserve the right to petition the finality of the restriction (see 37 CFR 1.144 and MPEP 818.03(c)).

III. THE CLAIM OBJECTION HAVE BEEN OVERCOME

The Examiner's request is not understood as there is no statutory basis for cancellation of non-elected subject matter prior to receipt of a final Office Action on the merits (see MPEP 821.01). In any event, as the applicants have established above that the restriction should be withdrawn, the objection has been rendered moot.

IV. THE 35 U.S.C. 112, 2nd PARAGRAPH REJECTIONS ARE OVERCOME

Claims 2-20 were rejected as allegedly being indefinite for being unclear if the method steps were to be completed in the recited order. (The remainder of the Examiner's explanation appears to be missing.) In order to advance prosecution, the applicants have numbered the steps as this does not serve to change the scope of the invention to one of ordinary skill in the art and still recites the same order as was originally presented.

However, the Examiner is reminded that the standard for applying 35 U.S.C. 112, second paragraph is described in MPEP 2173.02 which states:

"The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement." (emphasis added)

V. THE 35 U.S.C. 103(a) REJECTIONS HAVE BEEN OVERCOME

1. Claims 2-18 and 20 were rejected as allegedly being obvious over Ford et al. (U.S. Patent Application Publication 2002/0065242 - "Ford") in view of Caldwell et al. (U.S. Patent 5,516,703 - "Caldwell").

MPEP 2143.03 states in part that "To establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)". If a primary reference is missing one or more elements or limitations then there must be a teaching or suggestion to modify that reference.

As stated in MPEP 2143.03 (Suggestion or Motivation to Modify the References - The Prior Art Must Suggest the Desirability of the Claimed Invention) "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper.)" Simply put, obviousness is not established merely by collecting the necessary elements or limitations from isolated references. "Virtually all [inventions] are combinations of old elements...Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability.' *Sensotronics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996)." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998). However, Ford in view of Caldwell merely reflects a collection of elements which does not render the applicants' claimed invention obvious.

The Examiner describes the invention of Ford and acknowledges that Ford fails to teach a surface being hydrophobic. Caldwell is referred to for their teaching of a hydrophobic surface in order to provide a surface with a specific reactivity. The Examiner's motivation for making this combination is that one of ordinary skill in the art would have used a hydrophobic surface as taught by Caldwell to provide a surface with a high degree of reactivity and little or no background non-specific activity.

However, the Examiner's motivation for combining Ford and Caldwell emanates from her own opinion and not from any particular teaching or suggestion from either the Caldwell or Ford reference that directs to one of ordinary skill in the art that this specific element of Caldwell could be *substituted into Ford*, i.e. Caldwell would only be suggestive of using a hydrophobic surface as taught by Caldwell to provide a surface with a high degree of reactivity and little or no background non-specific activity for surfaces that are similar to Caldwell, not Ford. As stated in MPEP 2142 "[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." (emphasis added). Opinion is not a substitute for factual support.

There is also no explanation by the Examiner as to why it would have been obvious to one of ordinary skill in the art (especially when using the "as a whole" standard for considering the references and the applicants' claims, see MPEP 2142) to select one isolated element from Caldwell's invention for substitution into Ford. While the Examiner has the benefit of the applicants' claims before her when considering the Ford and Caldwell references, the hypothetical "one of ordinary skill in the art" does not have this luxury. Lacking the applicants' claims for guidance, the skilled artisan has no direction from within Caldwell to select one element (e.g. a hydrophobic surface) over any of the other elements of Caldwell's invention (e.g. (poly(ethylene oxide) blocks, poly(propylene oxide) center blocks, etc.). It is well known that "A prior art reference must be considered in its entirety, i.e. as a whole, *including portions that would lead away from the claimed invention.*" (see MPEP 2141.02) and that "*[i]t is impermissible* within the framework of section 103 to *pick and choose* from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965). In addition, one of ordinary skill in the art presented with the Ford and Caldwell references in the absence of the applicants' claims and considering the references as a whole would rightfully wonder what a method for the metallization of nucleic acid via nanoparticles produced *in situ* (Ford) had in common with a coating of hydrophobic surface to render them protein resistant (Caldwell).

Even if no motivation was required to modify the Ford reference and the Examiner could pick and choose elements at will to arrive at the applicants' invention, the combination of Ford and Caldwell would still not teach all of the applicants' claim

limitations because the Examiner has misinterpreted the meaning of col. 7, lines 19-30 from Caldwell. The statement that "[t]he modified polymeric surfactant is adsorbed upon a hydrophobic polymer substrate to provide a surface with specific reactivity" is NOT a teaching of a hydrophobic surface but the exact opposite, i.e. a hydrophilic surface. This is confirmed throughout the teachings of Caldwell, see e.g. col. 4, lines 4-7 - "The surface resulting from the modified polymer adsorbed on the hydrophobic substrate is hydrophilic and quite compatible with proteins that can be immobilized on the surface through reactive sites." Therefore, the combination of Ford and Caldwell would still lack a teaching for a hydrophobic surface in the final product as claimed by the applicants.

For any of the above reasons, the combination of Ford and Caldwell do not render the applicants' claimed invention to be obvious.

2. Claim 19 was rejected as allegedly being obvious over Ford et al. (U.S. Patent Application Publication 2002/0065242 - "Ford") in view of Caldwell et al. (U.S. Patent 5,516,703 - "Caldwell") and further in view of Berning et al. ("¹⁹⁸Au-Labelled Hydroxymethyl Phosphines as Models for Potential Therapeutic Pharmaceuticals", Nuclear Medicine & Biology, vol. 25: 577-583 (1998) - "Berning").

As claim 19 is dependent on claims 1 or 2, the arguments presented above would also apply here and claim 19 would be allowable should claims 1 and 2 be allowed.

Furthermore, while there are no limits in theory as to the number of references which can be combined to assert a *prima facie* case of obviousness, it should be quite evident that each subsequent addition of references strains the credulity that the applicants' claimed invention is "obvious". In the present case, the Berning reference is also used for an isolated element from within its teachings without considering the reference as a whole. As in Ford and Caldwell above, there is no teaching or suggestion to first select tris(hydroxymethyl)phosphine-gold from Berning and then to combine it in a process like Ford (i.e. Berning would only be predictive for teachings similar to Berning); the motivation for combination comes from the Examiner's opinion and not from any factual support from any of the Ford, Caldwell or Berning references.

For any of the above reasons, the combination of Ford, Caldwell and Berning does not render the applicants claimed invention to be obvious.

VI. THE DOUBLE-PATENTING REJECTION HAS BEEN OVERCOME

Claims 2-6, 11, 15 and 17-19 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 14 and 15 of co-pending application no. 10/210,812 (now U.S. Patent 6,884,587) or claims 1,4, 14-16 and 20 of co-pending application 09/990,049 in view of Caldwell et al. (U.S. Patent 5,516,703).

Although there are many similarities between an obviousness rejection and a rejection based on obviousness-type double patenting, a distinct difference between the two rejections is that the latter rejection only allows for a *comparison of the reference claims against the applicants' pending claims*. Moreover, when considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, *the disclosure of the patent may not be used as prior art* (see MPEP 803, section II. B. 1 and section III.).

For both the '812 and '049 applications, the Examiner concedes that the claims fail to teach a hydrophobic substrate. The fact that the Examiner needs the Caldwell reference to establish all of the elements and limitations of the applicants' claimed invention is *prima facie* evidence that a reference claim vs. pending claim analysis would not establish in the mind of a skilled artisan that an obviousness-type double patenting rejection exists.

REQUEST FOR INTERVIEW

In the interest of adhering to the tenets of compact prosecution and obtaining good customer service (see page 7 of the FY-2004 Performance and Accountability Report), the applicants request that the teachings of MPEP 707.07(j), sections II and III be applied, especially with regard to the offer of suggestion for correction by the Examiner if the rejections are upheld.

In accordance with MPEP 713.01, section III, should any issue remain as an impediment to allowance, an interview with the Examiner and SPE are respectfully requested; and, the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview ("An interview should normally be arranged for in advance, as by letter, facsimile, electronic mail, telegram or telephone call, in order to insure that the primary examiner and/or the examiner in charge of the application will be present in the office." *Id.*).

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
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